SEP 2 9 2000

K001056

SAFETY AND EFFECTIVENESS SUMMARY

*This summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990.

Olympic Medical
5900 First Ave. S.
Seattle, WA 98108
206-767-3500

Contact Person: Joseph Stefanile

Common or usual name of device ---------- Heat Lamp
Trade or proprietary name ---------- Olympic Warm-up$_{TM}$
Classification name (if known) ---------- 80 FOI
Predicate device(s) to which substantial equivalence is being claimed ---------- Olympic Warm-Lamp Model 41, Emerson Warming Light Series 96 Air-Shields, Free Standing (7830)

Device Description

1. Brief explanation of how the device functions.

   The Olympic Warm-up$_{TM}$ is a source of controllable radiant heat for use in the hospital or clinic. It provides temporary supplemental heat to the patient.

   The head assembly contains a rugged I.R. heating element. The heating element is enclosed by a double-wall enclosure. There is a protective screen in front of the heating element.

   The head assembly is fan cooled to keep the external enclosure temperatures low. The entire assembly is mounted on a counter-balanced arm assembly. The assembly may be aimed by the user by means of a handle.

2. Basic scientific concepts that form the basis for the device.

   The scientific principle behind a light bulb is that if a strong electric current is passed through a conducting filament (wire thread), the molecules in the filament become excited. As a result, the filament becomes hot, glows and emits heat and light.

   The I.R. heating element is similar, however, the electromagnetic spectral emissions are shifted to the longer wave-length region, yielding heat and very little light.

3. Significant physical and performance characteristics of the device. (e.g., device design and physical properties.)

   See the comparison chart, section 7, for physical characteristics.

   The performance characteristics of a heat lamp are best described in terms of heat output. See section 8 for results of heat measurement tests.

4. Intended Use of the device

   The Olympic Warm-up$_{TM}$ is a source of controllable heat for use in the hospital or clinic. It provides supplemental heat to the patient.

5. Does the indication statement (4) differ from those of the predicate device?

   Check one: ____ Differs (complete section 6)
   X Does not differ (skip to section 7)

6. Explanation of why the differences are not critical to the intended use of the device and why the differences do not affect the safety or effectiveness of the device.

   N/A

7. The technological characteristics of the device compared to the predicate product.

(See comparison chart next page)

Comparison Chart

	Olympic Warm-up™	Olympic Warm-Lamp Model 41	Emerson Series 96		Air-Shields Free Standing (7830)
Lamp Type		**I.R. – Quartz Tube**	**I.R. – Bulb Type**		**I.R. – Quartz Tube**
Method of Cooling	Fan forced air	Fan forced air	No active means... relies on radiation and convection		No fan
Protective Enclosure	Metal	Metal	Wire Mesh		Plastic
Protective Screen in Front of Lamp	Yes – Fine wire mesh	Yes – Fine wire mesh	Yes – Fine wire mesh		No
Aiming Means	Swivels and tilts - aimmable by user via handle	Swivels and tilts - aimmable by user via handle	Requires tool (screwdriver) to adjust		No
Total Wattage	825 Watts	720 Watts	500 Watts		625 Watts
Minimum Distance to Patient	36 inches	26 inches	28 inches		29 inches (est.)
Timer	Yes – 30 minute	Yes – 15 minute	No[1]	Yes – 15 minute[1]	Yes
Maximum Temperature*	108.4° F	111° F	104° F		111.2° F
Reflector Type	Separate (aluminum)	Separate (aluminum)	Part of bulb (glass)		Separate (aluminum)
Intensity Control	Standard	Standard	Optional		Yes
Height	73" Maximum 57" Minimum	80" Maximum 63" Minimum	95" Maximum 58" Minimum		77" Maximum 71" Minimum
Weight	110 lbs.	58 lbs.	35 lbs.		92 lbs.
Models	Mobile Floor Stand	• Mobile Floor Stand • Wall Mounted • Desk Mounted	• Mobile Floor Stand • Wall Mounted		Mobile Floor Stand

* AAMI standard test object, max. stabalized temp. [IEC ICD2:620(CO)71]
[1] Emerson Series 96 has 2 control configurations

8. A brief description of nonclinical tests and their results.

   Comparative temperature performance data was collected for the Olympic Warm-up and the light using the following test device: Olympic Warm Lamp, Emerson Series 96, and Air-Shields, Free Standing (7830).

   AAMI Radiant Test device, described in the AAMI document IEC ICD2 – "IEC draft international standard: 62D(CO)71 – medical electrical equipment, part 2: Particular requirements for the safety of infant radiant warmers."

The tests may be summarized as follows:

	Olympic Warm-up™	**Olympic Warm-Lamp Model 41**	**Emerson Series 96**	**Air-Shields Free Standing (7830)**
Maximum Temperature*	108.4° F	111° F	104° F	111.2° F

* Tested at maximum intensity and high line voltage (132-136 Vac).

9. A brief description of clinical tests submitted, referenced or relied on for 510(k) clearance.

   N/A

10. Conclusions drawn from non-clinical tests that demonstrate the device is safe, effective, and performs as well as or better than the legally marketed device.

    As data presented in #8 above shows, the Olympic Warm-up$_{TM}$ emits infrared energy equivalent to the predicate devices.

    All operator contact temperatures meet CSA-601 requirements.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 2 9 2000

Mr. Joseph Stephanile
Olympic Medical Corporation
5900 First Avenue
Seattle, Washington 98108

Re: K001056
Trade Name: Olympic Warm-up
Regulatory Class: II
Product Code: ILY
Dated: June 29, 2000
Received: July 3, 2000

Dear Mr. Stephanile:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general control provisions of the Act. The general control provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for Mark N Milhauser

Celia M. Witten, Ph.D., M.D.
Division Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K 001056

Device Name: OLYMPIC WARM-UP™

Indications For Use: The Olympic Warm-up™ is a source of controllable heat for use in the hospital or clinic. It provides supplemental heat to the patient.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mark N Milhous

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K 00 1056

Prescription Use X OR Over-the-Counter Use _____
(Per 21 CFR 801.109)